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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,740	04/05/2000	HIROSHI MURAKAMI	Q57531	5460

7590 09/24/2002

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EXAMINER

PARAS JR, PETER

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/24/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.


Office Action Summary

Application No.

09/462,740

Applicant(s)

MURAKAMI ET AL.

Examiner

Peter Paras

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Applicant's amendment filed on 6/27/02 has been entered. Claim 1 has been amended. Claims 1-3 and 6-8 are pending and are under current consideration.

Sequence Compliance

Applicants sequence listing in paper and computer readable forms has been entered. However, Applicants have not fully complied with the requirements of 37 C.F.R. 1.821-1.825, as the instant specification has not been amended to include sequence identifier numbers for the sequences listed on page 14. Applicant's failure to amend the specification did not prevent examination of the instant application. Any response to the instant Office action that does not meet the requirements of C.F.R. 1.821-1.825 will be considered non-responsive.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 6-8 as amended or originally filed are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The previous rejection is maintained for the reasons of record advanced on pages 2-5 of the Office action mailed on 12/27/01.

Applicant's arguments filed 7/27/02 have been fully considered but they are not persuasive. Applicants have submitted that the teachings of WO 97/12035 (included in the IDS of 7/27/02) enable the instant claims for xenotransplantation by showing some evidence of suppression of hyperacute rejection although WO 97/12035 exemplifies a different complement inhibitor, CD 59. See pages 3-4 of the amendment.

In response, the Examiner asserts that WO 97/12035 is not germane to the instant application because its teachings as Applicants have pointed out are directed to transgenic non-human mammals expressing a different complement inhibitor, CD 59. Moreover, as stated in the Office action of 12/27/01 the instant specification has not enabled the invention as claimed for xenotransplantation. See pages 3-5 of the Office action of 12/27/01. The specification has not provided any guidance, teachings, or working examples that demonstrate or otherwise correlate to the use of claimed transgenic non-human mammals in xenotransplantation. Since the specification is directed to xenotransplantation of cells or tissues from the claimed transgenic non-human mammals it is not clear how to otherwise use the claimed invention. The industrial uses of the claimed invention disclosed on pages 9-11 of the specification relate to xenotransplantation and do not provide adequate support for uses of the claimed invention other than for xenotransplantation. Furthermore, the art of xenotransplantation is unpredictable with respect to suppression of hyperacute rejection in organ transplant recipients. See Kuipers and Artip on page 4 of the Office action mailed on 12/27/01. Finally, the working examples provided by the instant specification

only relate to in vitro experimentation and do not appear to provide a nexus to xenotransplantation. See page 4 of the Office action mailed on 12/27/01.

Accordingly, the rejection is maintained for the reasons of record and as discussed above.

Claim Rejections - 35 USC § 103

Claims 1-3 and 6-8 as amended or originally filed are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosengard taken with Toyomura. The previous rejection is maintained for the reasons of record advanced on pages 6-7 of the Office action mailed on 12/27/01.

Applicant's arguments filed 6/27/02 have been fully considered but they are not persuasive. Applicants have argued that their effective priority date antedates the Toyomura reference. Applicants have provided a certified translation of their Japanese priority document in support of their arguments. Applicants go on to discuss that the Japanese patent teaches the creation of pMCP/DAF transgenic mice, which can be used for translation in pigs. See page 5 of the amendment.

In response, the Examiner asserts that the Toyomura reference is relevant in the instant rejection because Applicant's priority documents, namely PCT/JP98/02927, filed on 6/30/98, and Japanese application 9/205235, do not describe the invention being now claimed. In particular, it appears that the parent applications have only described the creation of a pMCP/DAF/CD55 transgenic mouse while the instant application has claims directed to pMCP/DAF/CD55 transgenic non-human mammals and has described the creation of pMCP/DAF/CD55 transgenic mice and pigs. In short, the

priority documents do not teach the creation of a pMCP/DAF transgenic pig and do not support Applicant's instantly claimed breadth to transgenic non-human mammals. Also, the teachings of the priority documents cannot be extended to the transgenic pig of the instant application because it appears that the transgene used to create the transgenic pig was not disclosed in the priority documents. Applicants have not provided any other arguments that are relevant to the instant rejection. It is maintained that Rosengard taken with Toyomura teach the instantly claimed invention. See pages 6-7 of the Office action mailed on 12/27/01.

Accordingly, the rejection is maintained for the reasons of record.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

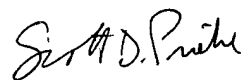
Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Patsy Zimmerman whose telephone number is (703) 308-0009.

Peter Paras, Jr.

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SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER